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CERTIFICATION OF COAL-TAR FOOD COLORS

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INTRODUCTION

The procedure for the certification of coal-tar food colors outlined in this circular supersedes that previously followed by the Department of Agriculture.

The Bureau of Chemistry is hereby authorized to certify coal-tar food colors which meet the accompanying requirements for certification.

R. W. DUNLAP,
Acting Secretary of Agriculture.

WASHINGTON, D. C., *July 11, 1925.*

PURPOSE OF CERTIFICATION AND USE OF CERTIFIED DYES

As ordinarily manufactured for textile or other industrial purposes, dyes often contain impurities, some of which are harmless whereas others are more or less toxic. These impurities may not detract from the value of the dyes for industrial use, but they would be highly objectionable in a substance designed for human consumption. Practically all dyes at one stage or another of their manufacture are treated with sulfuric or nitric acid, both of which are frequently contaminated with arsenic. The vessels in which the dyes are made may also contain arsenic. Unless special precautions are taken the dyes may therefore be seriously contaminated with arsenic compounds. If the manufacturing processes are carried on in vessels of lead or copper, appreciable quantities of these metals may be dissolved and contaminate the dye. Harmful intermediates and organic compounds are present in most industrial dyes. Uncombined intermediates and other organic compounds produced by side reactions during manufacture, even though comparatively

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harmless, are objectionable in food dyes, except in very small proportions. The standards of purity set for certified dyes necessitate special precautions in their manufacture and purification, in order that appreciable quantities of objectionable substances may not be present in the finished dyes. Certification by the Bureau of Chemistry implies not only that the dye itself is harmless, but that it is uncontaminated by poisonous substances.

The procedure of certification has been devised for the purpose of affording manufacturers of food colors and manufacturers of food products, as well as other consumers of food colors, a means of determining the suitability of these products for food use in so far as their purity and harmlessness are concerned. The use of color of any kind to conceal damage or inferiority in a food product is defined by the Federal food and drugs act as an adulteration, and, when damage or inferiority is concealed, the employment of artificial color is not permissible, even though certified colors are used and their presence is declared on the label. In general, where colors are legitimately used in foods and beverages a statement on the label of the presence of artificial color is required.

As unpermitted coal-tar dyes or permitted dyes which have not been certified are likely to be harmful in themselves or to contain harmful impurities, manufacturers who sell them for food purposes or who use them in coloring food products may render themselves liable to prosecution and the dyes or the foods colored with them liable to seizure under the Federal food and drugs act. The same objections apply to the use of mineral or inorganic coloring matters. Manufacturers who use organic coloring matters of natural origin, such as vegetable colors, should assure themselves that such substances are harmless in themselves and free from harmful impurities

WHEN A CERTIFIED DYE BECOMES UNCERTIFIED

When a container of a certified dye is opened, the guaranty of its purity can no longer apply, inasmuch as no one other than the person or firm breaking the package can further assume responsibility for its purity and identity. Certified dyes that have been repacked, either without mixing or with the admixture of other certified dyes or suitable diluents or both, therefore can not properly be marketed as certified dyes or mixtures, unless they are recertified in the proper manner (p. 7). Dealers, mixers, and repackers of dyes should be particularly careful to observe this fact. The use of the word "certified" or the use of batch numbers, lot numbers, and the like on repacked dyes or color mixtures that have not been recertified creates a misleading impression, constituting a violation of the Federal food and drugs act if the products are brought within its jurisdiction.

THE PERMITTED DYES

The following coal-tar dyes are accepted for certification as described on pages 4 to 11. (The first number in each line is that of the dye as listed in the Colour Index of 1924, published by the Society of Dyers and Colourists of England; the second number, in parentheses, is that appearing in former department announce-

ments and is the identifying number of the dye given in Green's "Systematic Survey of the Organic Coloring Matters," 1904 edition.)

Red shades:
80 (56) Ponceau 3R.
184 (107) Amaranth.
773 (517) Erythrosine.
Orange shade:
150 (85) Orange I.
Yellow shades:
10 (4) Naphthol yellow S.
640 (94) Tartrazine.
22 Yellow A B (benzeneazo-β-napthylamine).
61 Yellow O B (ortho-tolueneazo-β-naphthylamine).
Green shades:
666 (433) Guinea green B.
670 (435) Light green S F yellowish.
Blue shade:
1180 (692) Indigotine.

Yellow A B and Yellow O B are known as oil-soluble dyes, because they are soluble in edible oils but insoluble in water. The other nine dyes are soluble in water but insoluble in oils.

The original list of seven permitted dyes was selected after a critical study of the reports of pharmacological tests on the more important dyestuffs.[1] The other four dyes were added to the list after appropriate pharmacological and toxicological tests had proved them to be harmless.

DEFINITION OF TERMS

When used in these regulations,

Manufacturer means the person or firm responsible for the identity and purity of the product, or the accredited selling agent in the United States of such person or firm which is not resident within the jurisdiction of this Government. Such accredited agent must assume for his foreign principal all responsibilities which devolve upon the manufacturer resident within the United States.

Batch means that quantity of the dye which has received as a unit such treatment in the same manner and at the same time and place as shall render the product uniform in composition throughout its entire mass. The maximum size of a batch is limited only by the capacity of the equipment used to produce uniformity of composition.

Batch number is the number assigned by the manufacturer to the batch with his request for certification. It provides a convenient way of designating the various batches while they are undergoing examination in the Bureau of Chemistry. The batch number must appear on all affidavits and agreements submitted for that batch and on the label of the sample submitted for examination.

Mixture means a color which is made from two or more certified dyes without any other added substance, or a color made from one or more certified dyes mixed with a harmless diluent suitable for use in foods and not of itself a coloring matter.

[1] Hesse. Coal-tar colors used in food products. U. S. Dept. Agr., Chem. Bul. 147 (1912).

CERTIFICATION REQUESTED

When a manufacturer has prepared his first batch of a permitted dye for the purpose of requesting certification, a representative sample of the batch should be analyzed by the methods prescribed by the Bureau of Chemistry. If the analysis shows that the dye complies with the specifications of purity for that particular dye, he should execute a manufacturer's affidavit and agreement and have the examining chemist execute a foundation affidavit. The nature of the affidavits and agreement required are indicated in the following approved forms:

MANUFACTURER'S AFFIDAVIT

----------,
----------, *ss:*

Before me, a ----------, personally appeared the
(Title of officer administering oath.)
undersigned, in the county and State aforesaid, who, being first duly sworn, deposes and says: I, ----------, am ----------
(Name.) (State official title if officer of
----------,
corporation; if member of partnership, so state; if sole owner, so state.)
of ----------
(Name of corporation or partnership or name under which sole owner conducts business.)
of ----------; the material known as ----------
(Address.) (Name of dye.)
hereto attached was manufactured by ----------;
(Me or name of corporation or partnership.)
the material corresponds to the coloring matter numbered ---------- in Colour Index (1924), published by the Society of Dyers and Colourists of England; the accompanying affidavit, signed by ----------, contains
(Name of examining chemist.)
the report of an analysis of a fair, average sample drawn from batch number -----; the total weight of said batch is ---------- pounds; and the material hereto attached is a fair, average sample of said batch.

(Signature.)

Subscribed and sworn to before me, at ----------, this ------ day of ----------, 19 --.

[SEAL]

(Signature of officer administering oath.)

(Title of officer administering oath.)

MANUFACTURER'S AGREEMENT

If the batch mentioned in the foregoing affidavit is certified by the Bureau of Chemistry, the undersigned agrees to place plainly and conspicuously on the label, which shall in every instance be attached to the package put up by ---------- and containing any of the material
(Me or name of corporation or partnership.)
from said batch, the lot number assigned by the Bureau of Chemistry and the following statement:

> This certified dye contained when packed ------ per cent pure coal-tar dye and ------ per cent moisture.

The undersigned further agrees to keep available to representatives of the Bureau of Chemistry at all reasonable hours for five years from date of certification complete records of the disposition of said batch and each and every part of it, including dates of and number of pounds in each delivery or shipment or other disposition and names and addresses of the persons or firms receiving the dye from ----------.
(Me or name of corporation or partnership.)

(Signature.)

---------- ,
---------- , *ss:*

I hereby certify that on this ------ day of ----------, 19 --, before me, a ----------, ----------
(Title of officer.) (Name of person signing agreement.)
----------, of
(Sole owner, partner, or official title of officer of corporation.)
----------,
(Name of corporation or partnership or name under which sole owner conducts business.)
who is personally known to me and who is known by me to be
----------, of
(Sole owner, partner, or official title of officer of corporation.)
----------,
(Name of corporation or partnership or name under which sole owner conducts business.)
personally appeared and did acknowledge that he signed the above agreement.

[SEAL]

----------.
(Signature of officer taking acknowledgment.)

----------.
(Title of officer taking acknowledgment.)

FOUNDATION AFFIDAVIT

----------,
----------, *ss:*

Before me, a ----------, personally appeared the undersigned, in the county and State aforesaid, who being first duly sworn, deposes and says: I, ----------, residing at ----------,
(Title of officer administering oath.) (Name.) (Street address.)
in the city of ----------, county of ----------, State of ----------, have personally examined and tested for ----------, of the city of ----------,
(Full name of firm covered by manufacturer's affidavit.)
county of ----------, State of ----------, the sample described in the attached manufacturer's affidavit; the sample corresponds to the coloring matter numbered ---------- in Colour Index (1924), published by the Society of Dyers and Colourists of England; said sample consists of ----------
(Name of color.)
---------- only; it is free from harmful constituents; it contains no contamination due to imperfect or incomplete manufacture; and the following is a complete and accurate report of my chemical analysis and my interpretation of results: (Here insert a complete statement of all tests applied to determine the identity of the dye, the absence of harmful mineral, metallic, or organic constituents and the absence of contamination due to improper or incomplete manufacture. There should be set forth the quantity or volume of each material and reagent employed, its strength or concentration, temperature, duration of treatment, limits of delicacy of tests employed, and all other information necessary to enable other chemists to repeat accurately all work herein reported. For each test performed the conclusions drawn and the reason for these conclusions should be stated. This should be followed by a brief summary of the results obtained, preferably in a table of two columns of figures, one showing the percentages of the substances actually found and the other the ratio of these percentages to the percentage of dye. The methods of analysis used should be those described in Department of Agriculture Bulletin 1390, with such additions or revisions as may be made from time to time.)

(Signature.)

Subscribed and sworn to before me, at ----------, this ------ day of ----------, 19--.

[SEAL]

(Signature of officer administering oath.)

(Title of officer administering oath.)

These affidavits and agreement, attached to a 1-pound representative sample of the batch in the case of water-soluble dyes or a half-pound sample in the case of oil-soluble dyes, are sent to the Bureau of Chemistry. The samples submitted should be packed in suitable con-

tainers and labeled conspicuously with the name and address of the manufacturer, the name of the dye, the batch number, and the total weight in pounds of the batch. For convenience, most manufacturers label their batches of each permitted dye in a consecutive series. The label should be securely attached to the container.

CERTIFICATION GRANTED

Upon receipt of the sample and properly executed affidavits and agreement by the Bureau of Chemistry, the sample is examined chemically if the foundation affidavit indicates that the dye is of proper identity and purity. If the results obtained substantiate the claimed identity of the dye and its compliance with the standards of purity, a certificate assigning a lot number to the batch is issued by the bureau to the manufacturer. If the bureau's examination shows that the product does not conform to the requirements for certification, the batch is rejected for use in foods. The chemical examination and the certification or rejection of the batch usually take approximately two weeks.

LOT NUMBER

The lot number assigned on certification applies only to that particular batch of dye and to no other batch of the same or another dye. It is to be used by the manufacturer on each container in which the batch is packed for commerce. It is the manufacturer's guaranty that the dye has been certified and as such can apply only to those containers in which it was originally packed by him.

CERTIFICATION OF SUBSEQUENT BATCHES

The certification of subsequent batches of the same dye is accomplished in exactly the same way as the certification of the first batch, except that a supplemental affidavit is submitted instead of a foundation affidavit and a smaller sample is required. The facts necessary in the supplemental affidavit are indicated in the following approved form:

SUPPLEMENTAL AFFIDAVIT

----------,

----------, *ss:*

Before me, a ----------, personally appeared the
(Title of officer administering oath.)
undersigned, in the county and State aforesaid, who, being first duly sworn, deposes and says: I, ----------, residing at ----------
(Name.) (Street address.)
---------, in the city of ----------, county of ----------,
State of ----------, have personally examined and tested for ----
----------, of the city of ----------,
(Full name of firm covered by manufacturer's affidavit.)
county of ----------, State of ----------, the sample described in the attached manufacturer's affidavit; the sample corresponds to the coloring matter numbered ---------- in Colour Index (1924), published by the Society of Dyers and Colourists of England. Said sample consists of ----
---------- only; it is free from harmful constituents; it contains no
(Name of color.)
contamination due to imperfect or incomplete manufacture; and the following is a complete and accurate report of my chemical analysis, conducted in strict accordance with the detailed scheme of examination fully set forth in the foundation affidavit covering ----------, sworn to by ----------
(Name of dye.) (Me, or, if another

----------, on ----------, 19--: (Here insert a brief summary of the results obtained, preferably in the form of a table of two columns of figures, one showing the percentages of the substances actually found and the other the ratio of these percentages to the percentage of dye.)
(Chemist, give name.) (Date.)

(Signature.)

Subscribed and sworn to before me at ----------, this ------ day of ----------, 19--.
[SEAL]

(Signature of officer administering oath.)

(Title of officer administering oath.)

The manufacturer's affidavit and agreement are identical in form with those required for original certification.

Only a half-pound sample of the water-soluble dyes or a one-eighth pound sample of the oil-soluble dyes need be submitted with the manufacturer's affidavit and agreement and the supplemental affidavit. The general procedure in labeling and packing the sample and in issuing a certificate assigning a lot number or in rejecting the batch is the same as that for the certification of the first batch. The lot number assigned applies only to the particular batch for which it is issued and to no other batch of the same or another dye or mixture. The time necessary for certification or rejection of subsequent batches is usually shorter than that for original batches, ordinarily only about one week being required.

RECERTIFICATION OF REPACKED DYES

When a certified dye is repacked it should be recertified by submitting to the Bureau of Chemistry a secondary affidavit and agreement, with a one-fourth pound sample if the dye is water soluble or a one-eighth pound sample if oil soluble, packed and labeled as required for original certification. The facts required in the secondary affidavit and agreement are indicated in the following approved forms:

SECONDARY AFFIDAVIT (FOR REPACKS)

----------,
----------, *ss:*

Before me, a ----------, personally appeared the undersigned in the county and State aforesaid, who, being first duly sworn, deposes and says: I, ----------, am ----------
(Title of officer administering oath.) (Name.) (State official title if officer of

---
corporation; if member of partnership, so state; if sole owner, so state.)
----------, of ----------
(Name and address of corporation or partnership or

----------; the material
name under which sole owner conducts business.)
known as ---------- hereto attached is a fair, average sample of
(Name of dye.)
batch number ----------; said batch was made by repacking ----------
pounds of certified ----------, lot number ----------, obtained
(Name of dye.)
from ----------; the moisture content
(Name and address of person or firm from whom obtained.)
of said dye as reported by ---------- on ----------,
(Name and address of examining chemist.)

19--,[2] was ------ per cent; said batch was not otherwise mixed or treated in any way or manner.

(Signature.)

Subscribed and sworn to before me at ----------, this ---- day of ----------, 19--.

[SEAL]

(Signature of officer administering oath.)

(Title of officer administering oath.)

SECONDARY AGREEMENT (FOR REPACKS)

If the batch mentioned in the foregoing affidavit is certified by the Bureau of Chemistry, the undersigned agrees to place plainly and conspicuously on the label, which shall in every instance be attached to the package put up by ---------- and containing any of the material
(Me or name of corporation or partnership.)
from said batch, the lot number assigned by the Bureau of Chemistry and the following statement:

> This certified dye contained when packed ------ per cent pure coal-tar dye and ------ per cent moisture.

The undersigned further agrees to keep available to representatives of the Bureau of Chemistry at all reasonable hours for five years from date of certification complete records of the disposition of said batch and each and every part of it, including dates of and number of pounds in each delivery or shipment, or other disposition, and names and addresses of the persons or firms receiving the dye from ----------.
(Me or name of corporation or partnership.)

---.
(Signature.)

---,
---, *ss:*

I hereby certify that on this ------ day of ----------, 19--, before me, a ----------, ----------, ----------, ----------, of ----------
(Title of officer.) (Name of person signing agreement.) (Sole owner, partner, or official title of officer of corporation.) (Name of corporation or partnership or name under which sole owner conducts business.)
----------, who is personally known to me and who is known by me to be ----------, of ----------
(Sole owner, partner, or official title of officer of corporation.)
----------, personally appeared and did acknowledge that he signed the above agreement.
(Name of corporation or partnership or name under which sole owner conducts business.)

[SEAL]

---.
(Signature of officer taking acknowledgment.)

---.
(Title of officer taking acknowledgment.)

From the labels of the original dyes, which set forth the percentages of moisture and color at the time of original certification, and from the determination of moisture content at the time of repacking, the percentage of dye at the time of repacking can be readily calculated.

The general procedure in issuing a certificate assigning a lot number or in rejecting the batch is the same as that for the previous certification. The new lot number assigned applies to the particular repacked batch for which it is issued and to no other batch of the same or any other dye or mixture. Affidavit, agreement, and sample must be submitted for each batch repacked. Certification or rejection of batches of repacked dyes requires ordinarily about one week.

[2] Date of examination must be approximately that of repacking.

CERTIFICATION OF MIXTURES

Color mixtures should be certified before sale. No dyes or colors other than certified dyes may be used in preparing such mixtures for certification. Adequate precautions must be taken to make sure that the mixture is homogeneous throughout and that liquid mixtures are clear and free from sediment. Certified mixtures are ordinarily sold under trade names. The name chosen should be simple. Names which may be ambiguous or misleading should be avoided.

Certification of color mixtures is accomplished by submitting to the Bureau of Chemistry a secondary affidavit and agreement, with a one-fourth pound representative sample of the mixture, packed and labeled as required for original certification, except that the label may bear the trade name in lieu of the names of the dyes present. The facts required in the secondary affidavit and the agreement are indicated in the following approved forms:

SECONDARY AFFIDAVIT (FOR MIXTURES)

----------,
----------, *ss:*

Before me, a----------, personally appeared the undersigned in the county and State aforesaid, who being first duly sworn, deposes and says: I, ----------, am ----------
(Title of officer administering oath.) (Name) (State official title if officer of corporation; if member of partnership, so state; if sole owner, so state.)
of----------;
(Name and address of corporation or partnership or name under which sole owner conducts business.)
the material known as---------- hereto attached is a fair, average sample of batch number----; said batch was made by mixing ---------- pounds of certified ----------, lot number ----------, obtained from ---------- (repeat for each dye or mixture used) and ------ pounds ---------- of (repeat for each diluent used); said batch was made from these ingredients and none other; the moisture content of each of said ingredients used in making said batch as reported by ---------- on ----------, 19--,[3] was as follows:
(Name of mixture.) (Name of dye or mixture.) (Name and address of person or firm from whom obtained.) (Name of diluent.) (Name and address of examining chemist.)

----------, lot number --------, ------- per cent moisture;
(Name of dye.)
----------, lot number --------, ------- per cent moisture;
(Name of dye.)
----------, ------, per cent moisture. The total weight of said batch is
(Name of diluent.)
------ pounds; and said batch was thoroughly mixed to insure uniformity.

---------- (Signature.)

Subscribed and sworn to before me, at ----------, this ------ day of ----------, 19--.

[SEAL]

---------- (Signature of officer administering oath.)

---------- (Title of officer administering oath.)

SECONDARY AGREEMENT (FOR MIXTURES)

If the batch mentioned in the foregoing affidavit is certified by the Bureau of Chemistry, the undersigned agrees to place plainly and conspicuously on the label, which shall in every instance be attached to the package put up by

[3] Date of examination must be approximately that of mixing.

---------- and containing any of the ma-
(Me or name of corporation or partnership.)
terial from said batch, the lot number assigned by the Bureau of Chemistry and the following statement:

> This certified dye contained when packed ------ per cent pure coal-tar dye and ------ per cent moisture. (No reference need be made to percentage of moisture in liquid and paste mixtures.)

The undersigned further agrees to keep available to representatives of the Bureau of Chemistry at all reasonable hours for five years from date of certification complete records of the disposition of said batch and each and every part of it, including dates of and number of pounds in each delivery or shipment or other disposition and names and addresses of the persons or firms receiving the dye from ----------.
(Me or name of corporation or partnership.)

(Signature.)

----------,
----------, *ss:*

I hereby certify that on this ------ day of ----------, 19--, before me, a
---------- ----------, ----------
(Title of officer.) (Name of person signing agreement.) (Sole owner, partner, or official title of office of corporation.)
of ----------,
(Name of corporation or partnership or name under which sole owner conducts business.)
who is personally known to me and who is known by me to be----------
----
(Sole owner, partner, or official title of officer of corporation.)
of ----------,
(Name of corporation or partnership or name under which sole owner conducts business.)
personally appeared and did acknowledge that he signed the above agreement.

[SEAL]

(Signature of officer taking acknowledgment.)

(Title of officer taking acknowledgment.)

From the labels of the original dyes, which set forth the percentages of moisture and color at the time of original certification, from the determination of the moisture in the dyes and diluents at the time of mixing, and from the weight of each dye and diluent used in preparing the mixture, the percentages of moisture and dye in the finished mixture can be readily calculated. Statements of the percentage of moisture in liquid and "paste" mixtures are not required, but such statements must be given on the labels of all "dry" mixtures.

Formulas for mixtures are held confidential by the Bureau of Chemistry.

The general procedure in issuing a certificate assigning a lot number or in rejecting the batch is the same as for the original certification of the dyes. The lot number assigned applies only to that particular batch of the mixture for which it is issued and to no other batch of the same or other mixture or straight dye. Affidavit agreement, and sample must be submitted for each batch of mixture made.

Certification or rejection of batches of mixtures requires ordinarily about one week.

A certified mixture may be repacked and recertified, or it may be used as a constituent of another mixture for which certification is requested. Samples of repacked mixtures submitted with requests for recertification should be packed and labeled in accordance with

the procedure outlined for the original certification of mixtures, and the procedure otherwise is identical with that of original certification, except that the form of secondary affidavit and agreement required for recertification of repacked dyes is used, substituting the words "certified mixture" for "certified dye," and in the case of liquid and "paste" mixtures the percentage of moisture need not be reported in the affidavit or covered in the agreement.

CHANGES IN FORMULAS OF MIXTURES

Neither the name chosen nor a keyed modification of it may be used by the same person or firm for any other mixture made according to a different formula; provided, however, that, if reasons justifying a change in the formula of a certified mixture having an established trade name arise, the mixer or a responsible officer of the mixing firm may submit an affidavit, setting forth the facts on which the request for the change is based and stating that all the material made under the old formula has passed into consumption. If the facts given in the affidavit are deemed sufficient to justify an alteration in formula, approval will be given to the change.

GENERAL LABELING REQUIREMENTS

In addition to the labeling covered by the agreement submitted with samples for certification, the general provisions of the Federal food and drugs act regarding labels should be observed if the dye is distributed in interstate commerce. These require that the containers bear a plain and conspicuous statement of the quantity of the contents and prohibit the use of statements, designs, or devices that are false, misleading, or deceptive. Information concerning the requirements of the laws of States in which the color may be sold should be obtained from the responsible State officials, a list of whom will be furnished by the Bureau of Chemistry on application.

ADMISSION OF ADDITIONAL DYES

To be considered suitable for inclusion in the list of permitted coal-tar food colors, a dye must not be protected in any way by unexpired patents covering either the dye itself or the only known methods of preparing it or any of its intermediates. Its complete process of manufacture must have been described in some recognized scientific publication.

Manufacturers wishing to have a dye added to the permitted list should prepare the dye in as pure a form as possible and submit to the Bureau of Chemistry a manufacturer's affidavit and agreement, a foundation affidavit, and a detailed report by one or more reputable pharmacologists and toxicologists on the pharmacological and toxicological properties of the dye. When a knowledge of the process of manufacture is necessary to determine the identity of the dye, the submission in the manufacturer's affidavit of a complete description of certain steps or all steps in the manufacturing procedure may be required. To these reports should be attached a 5-pound sample of the dye taken from the same batch as that from which the sample used for analysis and pharmacological and toxicological investigations

was obtained. If the data submitted indicate the suitability of the dye for food use, the Bureau of Chemistry proceeds with chemical, pharmacological, and toxicological examinations of the sample. If these investigations show that the dye is harmless and of suitable purity, it is added to the permitted list, provided need for a new dye can not be met by dyes already on the list, or other sufficient reason obtains. The time required for these investigations is necessarily long; in most cases about two years will probably be needed.

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